Application No.: 10/722,102 Examiner: P. Philogene

Amendments to the Claims

(Currently amended) A method of performing surgery on replacing at least a portion of a
patient's knee including a femur and a tibia, the method comprising the steps of:

making an incision in a knee portion of a leg of the patient <u>sized smaller than the portion of</u> the knee to be replaced;

expanding the incision from an unexpanded configuration to an expanded configuration by applying force against opposite edge portions of the incision;

determining a position of a cutting guide using references derived independently from an intramedullary device;

positioning a cutting guide using the determined position, passing the cutting guide through the expanded incision and on a surface of a distal end portion of [[the]] an unresected femur, the cutting guide secured to the bone free of an extramedullary or intramedullary alignment rod, the cutting guide sized to be received in the expanded configuration;

moving a cutting tool through the incision into engagement with a guide surface on the cutting guide; and

eutting forming at least an initial cut on the femur by moving the cutting tool along the guide surface[[,]];

attaching a replacement portion of the knee to the cut surface.

wherein the cutting guide is positioned free of an extramedullary or intramedullary alignment rod using navigation references derived from the surface of the bone to be cut, said navigation references derived independently from an intramedullary device.

(Previously presented) The method of claim 1 wherein the surface is a medial or lateral side of the distal end portion of the femur.

(Canceled)

 (Currently amended) The method of claim 1 wherein a computer navigation system is used in the positioning determining step.

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(Original) The method of claim 1 wherein the positioning step includes removably attaching the cutting guide to the side surface of the distal end portion of the femur.

(Original) The method of claim 5 wherein the cutting guide is removably attached with first and second pins extending through holes in the cutting guide and into the femur.

 (Original) The method of claim 1 wherein the guide surface comprises a plurality of straight guide segments.

8. (Original) The method of claim 7 wherein the plurality of straight guide segments comprises:

a distal guide segment disposed in a plane which extends perpendicular to a longitudinal central axis of the femur and extends through lateral and medial condyles of the femur;

an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the femur; and

a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

9. (Canceled)

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10. (Original) The method of claim 1 wherein said step of cutting the femur includes utilizing the guide surface on the cutting guide to guide the cutting tool during making of an initial portion of a cut in the femur, and completing the cut in the femur while guiding the cutting tool with a surface formed during making of the initial portion of the cut in the femur.

- 11. (Previously presented) The method of claim 10 wherein the cutting guide is positioned on a side surface of the distal end portion of the femur during completion of the cut.
- 12. (Previously presented) The method of claim 10 wherein the cutting guide is removed from a side surface of the distal end portion of the femur after making the initial portion of the cut and before completion of the cut.
- 13. (Currently amended) A total knee replacement cutting guide for forming a cut surface on a bone in preparation to receive a total joint replacement component comprising:
- a disposable cutting guide member fabricated from a polymeric material and designed customized for a single use bone, disposable as no longer useful after the bone for which it has been customized has been cut and thereby changed, having a body dimensioned for attachment to a surface of an end portion of the bone free of an extramedullary or intramedullary alignment rod; and
- at least one guide surface dimensioned for engagement with a cutting tool to thereby direct the cutting tool:
- wherein the design of said cutting guide, the cutting guide being both polymeric and disposable, is readily modified in successive iterations for new or customized instrumentation.
- 14. (Original) The total knee replacement cutting guide of claim 13 wherein the guide member attaches to either a medial or lateral side surface of the end portion of the bone.

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15. (Original) The total knee replacement cutting guide of claim 13 wherein the at least one guide surface includes a distal end surface having opposite ends spaced apart by a distance which is less than a distance that the total joint replacement component extends across the bone when implanted.

16. (Original) The total knee replacement cutting guide of claim 15 wherein the guide member has an aperture for receiving a pin to thereby secure the guide member to the bone.

17. (Original) The total knee replacement cutting guide of claim 16 wherein the at least one guide surface includes:

an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the femur; and

a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

18. (Original) The total knee replacement cutting guide of claim 16 wherein the cutting guide is a non-captured cutting guide.

19. (Currently amended) A method of performing surgery on replacing at least a portion of a joint in a patient including a first bone and a second bone, the method comprising the steps of:

fabricating a customized cutting guide for the patient based on preoperative and clinical information:

fabricating a disposable cutting guide, designed for a single use from a polymeric material, and modified for updated or customized instrumentation:

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making an incision proximal to the joint in the patient, the incision sized smaller than the portion of the joint to be replaced;

determining a position of a cutting guide using references derived independently from an intramedullary device;

positioning the cutting guide <u>using the determined position</u>, <u>passing the cutting guide</u> through the incision and on a <u>side</u> surface of an end portion of the <u>first</u> an <u>unresected</u> bone <u>of the</u> joint before the anterior surface of said first bone is resected;

moving a cutting tool through the incision into engagement with a guide surface on the <u>positioned</u> cutting guide;

cutting the first unresected bone of the joint for the first time, by moving the cutting tool along the guide surface[[,]];

disposing of the cutting guide, as it is no longer safely usable or useful in a subsequent procedure, the cutting guide having been contaminated, or the bone for which it was custom fabricated having been cut and therefore changed.

wherein the cutting guide is positioned using navigation references derived from the surface of the bone to be cut, said navigation references derived independently from an intramedullary device.

20. (Previously presented) The method of claim 19 wherein the side surface is a medial or lateral side of the end portion of the first bone.

21. (Canceled)

- 22. (Currently amended) The method of claim 19 wherein a computer navigation system is used in the positioning determining step.
- 23. (Original) The method of claim 19 wherein the positioning step includes removably attaching the cutting guide to the side surface of the end portion of the first bone.
 - 24. (Original) The method of claim 23 wherein the cutting guide is removably attached

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with first and second pins extending through holes in the cutting guide and into the first bone.

25. (Original) The method of claim 19 wherein the guide surface comprises a plurality of straight guide segments.

26. (Original) The method of claim 25 wherein the plurality of straight guide segments comprises:

a distal guide segment disposed in a plane which extends perpendicular to a longitudinal central axis of the first bone;

an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the first bone; and

a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

27. (Canceled)

28. (Original) The method of claim 19 wherein said step of cutting the first bone includes utilizing the guide surface on the cutting guide to guide the cutting tool during making of an initial portion of a cut in the first bone, and completing the cut in the first bone while guiding the cutting tool with a surface formed during making of the initial portion of the cut in the first bone.

29. (Original) The method of claim 28 wherein the cutting guide is positioned on the side surface of the end portion of the first bone during completion of the cut.

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30. (Original) The method of claim 29 wherein the cutting guide is removed from the side surface of the end portion of the first bone after making the initial portion of the cut and before completion of the cut.

- 31. (Previously presented) The method of claim 1, wherein said incision is between about seven and about thirteen centimeters
- 32. (Currently amended) The method of claim 1, where said positioning determining step further includes the step of using light beams.
- 33. (Previously presented) The method of claim 1, wherein in said step of making an incision, said incision is offset from the center of said knee area.
- 34. (Previously presented) The method of claim 13, wherein said at least one guide surface includes a guide surface corresponding to each guide surface required by said joint replacement component.
- 35. (Previously presented) The method of claim 19, wherein after said step of cutting, further including the steps of:

removing said cutting guide; and,

guiding said cutting tool using cuts formed in said cutting step to complete said cuts.

- 36. (Previously presented) The method of claim 19, wherein in said step of positioning, said cutting guide is sized smaller than said side surface.
- 37. (Previously presented) The method of claim 19, wherein after said step of positioning, further including the step of:

aligning said cutting guide using markings on said side surface.

38. (Canceled)

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39. (Previously presented) The cutting guide of claim 13, wherein alignment of said cutting guide is performed by means selected from the group consisting of: computer navigation,

preoperative imaging, and extramedullary alignment.

40. (New) The method of claim 1, wherein the determining step includes adjusting the determined position to correct a deformity of the joint.

41. (New) The method of claim 1, wherein the portion of a patient's knee replaced is at least a portion of an articulating surface of the joint.

42. (New) The method of claim 19, wherein the cutting guide is mounted on an exterior surface of the skin, affixed to the bone with percutaneous pins.